Understanding Neuromodulation of the Stroke Brain

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Ethical review	Approved WMO
Status	Completed
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON48250

Source
ToetsingOnline

Brief title
UNOS

Condition

- Embolism and thrombosis

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Biomedical MR Imaging and Spectroscopy Group, Center for Image Sciences
Source(s) of monetary or material Support: Netherlands Organisation for Scientific Research/Netherlands Organisation for Health Research and Development. ZonMw/NWO

Intervention

Keyword: motor impairment, neuromodulation, stroke

Outcome measures

Primary outcome

The primary outcome measures will be the changes in RMT, IHI, iSP and ICI in response to contralesional cTBS. The primary outcome measures are described below:

Secondary outcome

1. The second secondary outcome parameter is the difference in change in RMT, IHI, iSP and ICI in response to contralesional cTBS treatment between the subacute phase and the chronic phase after stroke.

2. The first secondary outcome parameter is the difference in RMT, IHI, iSP and ICI between the population of stroke patients and healthy age-matched controls at two different time points.

3. The relationship of the aforementioned electrophysiological parameters with sensorimotor function test scores (ARAT/FM), white matter integrity (based on MRI), functional network organization (based on fMRI).

Study description

Background summary

Many acute stroke patients do not recover completely from motor impairment of the upper extremities. Previous studies show that motor impairment is associated with disrupted activity in the motor network of the brain. Non-invasive brain stimulation techniques, such as transcranial magnetic stimulation (TMS), can be used to restore disrupted brain activity and to facilitate the recovery of motor function in patients with stroke. Previous

research shows that continuous theta burst stimulation (cTBS), an inhibitory form of TMS, has a positive effect on the recovery of motor function in patients with stroke. However, a substantial variability exists in the reponse to this type of treatment. Additionally, little is known about the working principle of cTBS treatment. The current hypothesis is that contralesional cTBS treatment directly or indirectly modulates interhemispheric inhibition and intracortical inhibition. We also hypothesize that the interhemispheric imbalance in inhibition is different in the subacute phase after a stroke compared to the chronic phase.

Study objective

The objective of this study is to determine whether contralesional cTBS treatment modulates the interhemispheric imbalance in excitability or local or transcallosal inhibitory processes in the motor network of a population of stroke patients compared to healthy age-matched controls. 10 healthy controls as part of a pilot study.

Study design

This is an observational cohort study in which we will determine the direct electrophysiological effect of contralesional cTBS in patients with a stroke compared to healthy age-matched controls. We will do this at two different timepoints after stroke onset: in the subacute phase and the chronic phase. At both timepoints we will perform the same measurements. Firstly, we will assess a number of electrophysiological measurements and other tests in order to quantify the level of motor impairment. Next, the patient will undergo 40 second cTBS treatment after which the direct electrophysiological effect will be assessed by repeating the electrophysiological measurements. Patients and healthy participants also have the oppertunity to undergo an MRI scan.

Study burden and risks

The risk of participation in this study is negligible. Sensorimotor function testing, single pulse TMS and MRI have been performed safely in many patients over the last decades. The side effects of TMS consist of mild and transient headache or dizziness (risk: 1.1%). The risk of an epileptic seizure is very rare (risk: 0.02%). Some patients may experience claustrophobia during MRI acquisition.
We are aware of the burden on patients when they undergo these diagnostic procedures in an early stage of recovery. However, these data can provide valuable insight on post-stroke motor recovery and the role neuromodulation treatment in stroke patients, which can potentially be used to individualize and improve future rehabilitation treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adult patient age >= 18;
2. First-ever ischemic stroke in one hemisphere;
3. Unilateral paresis of an upper extremity with at least a palpable voluntarily muscle contraction of the deltoid muscle and a maximum Motricity Index (MI) of the hand of 25 (i.e. less force in the affected hand during performance of an opposing thumb movement task compared to the unaffected hand);
4. Inclusion possible between 3 weeks and 3 months after stroke onset;
5. Signed informed consent.

Exclusion criteria

1. Other disabling medical conditions (severe heart disease, severe head trauma, severe mental illness);
2. Severe deficits in communication, memory or understanding which could impede participation, as determined by the treating physician;
3. Contraindications for TMS and MRI (ferrous objects in or around the body, history of epilepsy, drug or alcohol abuse over a period of 6 months prior to the experiment, pregnancy).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-01-2020
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	24-01-2019
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL67438.041.18

Study results

Date completed: 19-10-2021

Actual enrolment: 13

Summary results
Trial ended prematurely